



Shilpa Medicare Limited

Corporate & Admin Office:

"Shilpa House", # 12-6-214/A-1, Hyderabad Road,
Raichur – 584 135, Karnataka, India
Tel: +91-8532-238704, Fax: +91-8532-238876
Email: info@vbshilpa.com, Web: www.vbshilpa.com
CIN: L85110KA1987PLC008739

Dated: 1st November, 2021

Corporate Relationship Department,
BSE Limited
Phiroze Jeejeebhoy Towers,
Dalal Street, Fort,
Mumbai-400 001

National Stock Exchange of India Limited
Exchange Plaza, 5th Floor,
Plot No.C/1, G Block
Bandra Kurla Complex, Bandra (E)
MUMBAI-400 051

Sub: Intimation U/R 30 of the SEBI (LODR) Regulations 2015- Reg.

Ref: Stock Code: NSE: SHILPAMED/BSE-530549

Shilpa Medicare Limited enters Phase I Clinical Trial for its New Biological Entity, recombinant Human Albumin

Dear Madam/Sir,

This is to inform you that Shilpa Medicare Limited ('SML' or 'the Company'), via its wholly owned subsidiary, Shilpa Biologicals Pvt Ltd (SBPL), has been permitted to conduct a Phase I human clinical study on its flagship novel product – **recombinant Human Albumin (NavAlbumin)**, by the Central Drugs Standard Control Organisation (CDSCO).

The product, is a synthetically developed product as compared to the current process of drawing the same from blood plasma and is backed by **granted global patent**. It is designated a "**New Biological Entity**" and is amongst the first indigenously developed novel molecules entering clinical studies - a significant milestone for the company and potentially large impact for the nation. The Company continues to strengthen its patent protection around the product to ring fence it from any potential competition.

The market for plasma Albumin as a drug is estimated at US\$5.5billion globally and growing at an average of 6% per annum. While India and Asia are the largest markets for the product by volume, the market for Albumin has been dogged by significant supply and safety constraints. The Company's novel product is expected to have the following advantages compared to the existing product drawn from blood plasma:

1. Predictable supply chain, as it is produced from a scalable fermentation processes – likely to enhance the market size for the product
2. Significantly higher degree of purity
3. Free from any potential contamination from HIV/HBV/HCV/Prions – since chemically defined media components are used throughout in its production

NavAlbumin, when approved for human use, will be used as a volume expander in indications like Liver Cirrhosis, major surgeries / bleeds. NavAlbumin is expected to disrupt the Albumin market in much the same way as Recombinant Factor VIII did to the plasma Factor VIII market in the early part of this century wherein Recombinant Factor VIII ended up capturing over 80% of the market share in less than a decade.

Apart from its uses as a drug, NavAlbumin has significant uses as:

- a pharmaceutical excipient,
- vaccines/protein stabilizer and
- in the emerging gene and cell therapy markets.

The company is now using this as a platform for some of its novel formulations.

Additionally, the company will be collaborating with other innovator companies globally in developing novel drugs and temperature stable formulations using NavAlbumin. Initial trials at potential customers have been extremely encouraging and the company hopes to see traction in the near future with global customers.

The product has undergone rigorous characterisation and preclinical testing at SBPL's development centre. This major milestone is culmination of 12 years of development work conducted from its integrated biologics R&D cum Manufacturing center at Dharwad, Karnataka. The program has been supported in part via grants / soft loans from the Department of Biotechnology, through BIRAC. The company views NavAlbumin as “Pipeline in a product” catering to various market segments by same product.

If approved as a drug after the human trials, NavAlbumin is expected to reach the market in 2023.



Shilpa Medicare Limited

Corporate & Admin Office:

“Shilpa House”, # 12-6-214/A-1, Hyderabad Road,
Raichur – 584 135, Karnataka, India

Tel: +91-8532-238704, Fax: +91-8532-238876

Email: info@vbshilpa.com, Web: www.vbshilpa.com

CIN: L85110KA1987PLC008739

The biologics business has been identified as a strategic growth engine by SML and it has made significant investments in setting up a high end, flexible biologics facility in SBPL. The company has recently entered into CDMO tie-ups with Cadila Healthcare Ltd and Dr. Reddy’s Laboratories Ltd for production of Covid-19 vaccines.

The facility at Dharwad would cater to the requirements of the fast-growing biologics field, that include the DNA vaccine, adenoviral, subunit vaccines, monoclonal antibodies & fusion proteins. The company is also in the process of setting up a world class 150,000 Liter fermentation capacity based NavAlbumin GMP production facility – which is expected to be completed in the latter half of 2022 – in time to enable the company to penetrate the global markets with NavAlbumin aggressively.

This is for your information and doing the needful.

For Shilpa Medicare Limited.

V V Krishna

Chaitanya

Digitally signed by
V V Krishna
Chaitanya
Date: 2021.11.01
10:13:22 +05'30'

V V Krishna Chaitanya
Company Secretary